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REMARKS

I. Status of Claims

Upon entry of this amendment, claims 1-27 and 29-37 are pending. Claims 28 and 38 have been canceled. Claims 14-22 and 37 have been withdrawn. Claims 14 and 37 have been withdrawn but include proposed amendments to be consistent with similar claims which have been amended to overcome rejections. Claims 1, 7, 23, 25-27, 29, and 34 have been amended.

Claims 1, 7, 14, 23, and 37 have been amended to recite "a nucleotide sequence hybridizing to SEQ ID NO: 2 under very high stringent wash conditions comprising at least one wash at 0.1x SSC, 0.1% SDS, at 60°C for 15 minutes." Support for the claim amendment may be found in the specification, for example, at paragraphs [0009] and [0062] of the published application.

Claims 25-26 have been amended to recite, "a recombinant nucleic acid." Support for these amendments may be found in the specification, for example, at paragraph [0009] of the published application. Claim 27 has been amended to recite "a recombinant nucleic acid comprising a nucleic acid sequence that is at least 90% identical to SEQ ID NO:2. Support for this amendment may be found in the specification, for example, at paragraph [0009] of the published application. Claim 29 has been amended to be consistent with the amended claim set.

Claim 1 has also been amended to recite "PHYTOCHROME AND FLOWERING TIME 1 (PFT1). Support for this amendment can be found in the specification, for example, at paragraph [0008] of the published application.

Claim 34 has been amended to be directed towards a seed comprising a recombinant expression vector. Support for this amendment can be found in the specification, for example at paragraph [0102] of the published application.

No new subject matter has been added, thus entry of the amendments is respectfully requested.

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II. Restriction Requirement

The Office has not found Applicant's traversal of the restriction requirement persuasive because the term "stringent" is allegedly not defined in the claim amendments, and is therefore interpreted by the Office to mean low stringency conditions. Thus the Office asserts that Halliday teaches the recited technical feature.

To the extent the restriction applies to the amended claims, Applicants respectfully maintain traversal of the lack of unity rejection. Under 37 C.F.R. 1.475, the requirement of unity of invention can be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In their instantly amended form, the claims are either directed to a PFT1 protein, wherein the protein is encoded by a nucleotide sequence hybridizing to SEQ ID NO: 2 under very high stringent wash conditions comprising at least one wash at 0.1x SSC, 0.1% SDS, at 60°C for 15 minutes or has an amino acid sequence that hybridizes to SEQ ID NO: 2 under very high stringent wash conditions comprising at least one wash at 0.1x SSC, 0.1% SDS, at 60°C for 15 minutes or encodes a protein which has an amino acid sequence at least 45% identical to SEQ ID NO: 3; or a recombinant nucleic acid comprising a nucleotide sequence encoding SEQ ID NO: 3 or that is at least 90% identical to SEQ ID NO: 2. Halliday thus fails to teach such a PFT1 gene or protein.

In view of the above, Applicants respectfully assert that the instantly pending claims have a special technical feature in common. As such, all claims have unity of invention and Groups I-V can readily be examined together. Applicants thus respectfully request withdrawal of the restriction requirement.

III. Specification

The Examiner has objected to the specification for allegedly not incorporating SEQ ID

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NOs when referring to nucleic acid or amino acid sequences, for example no sequence identifiers are used in Figure 9.

The specification has been amended to clarify the identity of the sequences. The brief description of Figure 9A-C has been amended to include sequence identifiers for the sequences of OsPFTI, SoPFTI, MtPFTI, SbPFTI, and AtPFTI and to correct a typographical error. Support for this amendment is found throughout the specification, and in particular, in Figure 9A-C. No new subject matter has been added, thus entry of the amendment is respectfully requested.

In view of the amendments, rejection of the objection is respectfully requested.

IV. Information Disclosure Statement

Applicants acknowledge the Examiner's statement that only the titles listed in the International Search Report have been considered. Applicants will resubmit an Information Disclosure Statement with the references cited in the International Search Report for the Examiner's consideration

V. Claim Objection

The Examiner has objected to claim 27 for allegedly reciting "sequence hybridizing" instead of "sequence that hybridizes". As amended, claim 27 recites "a recombinant nucleic acid sequence that hybridizes." Applicants therefore respectfully request that the Examiner withdraw the objection to claim 27.

The Examiner has also objected to claim 1, line 2 for not writing out PHYTOCHROME AND FLOWERING TIME1 in capital letters. As amended, claim 1, line 2 recites "PHYTOCHROME AND FLOWERING TIME 1 (PFT1) protein in a plant." Applicants therefore respectfully request that the Examiner withdraw the objection to claim 1.

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VI. Claim rejections - 35 U.S.C. § 112, 2nd Paragraph

Claims 1-5, 7-8, 10-13, 23-24, 27, 29-36 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office contends that claims reciting "stringent" are indefinite because no metes and bounds have been set forth for "stringent wash conditions."

Applicants respectfully assert that the rejection is moot in view of the instantly pending claims 1, 7, 14, 23, 27, and 37, which recite "very high stringent wash conditions comprising at least one wash at 0.1x SSC, 0.1% SDS, at 60°C for 15 minutes." Applicants therefore respectfully request that this basis for rejection be withdrawn.

VII. Claim Rejections - 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1-13, 23-24 and 27-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a recombinant nucleic acid sequence comprising SEQ ID NO: 2 or comprising a nucleotide sequence encoding SEQ ID NO: 3, and an expression vector comprising said recombinant nucleic acid operably linked to a promoter, and a transgenic plant comprising said vector wherein the plant has an early flowering phenotype compared to a wild-type plant, and a method for decreasing flowering time in a plant comprising transforming a plant with said vector; allegedly does not reasonably provide enablement for any nucleic acid sequence exhibiting less than 100% sequence identity to SEQ ID NO: 2 or any nucleic acid sequence encoding a protein exhibiting less than 100% sequence identity to SEQ ID NO: 3 and plant transformation therewith, or any method comprising said nucleic acid sequence, or any method of modulating at least one photosensitive trait in a plant comprising said nucleic acid sequence, or wherein said sequence encodes SEQ ID NO: 2. The specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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To the extent the rejections are applicable to the amended claims, Applicants respectfully traverse the rejection and its supporting remarks. As Applicants continue to traverse the restriction requirement and its supporting remarks, when applicable, the withdrawn claims are also addressed.

The legal standard for determining enablement was established by the Supreme Court, in Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916), to be whether undue or unreasonable experimentation is required to make and use the claimed invention. In In re Wands it was indicated that undue experimentation would be evaluated based on eight factors: the breadth of the claims; the level of predictability in the art; the amount of direction or guidance provided; the state of the prior art; the quantity of experimentation necessary to make and use the claimed invention based on the content of the disclosure; the existence of working examples; the nature of the invention; and the level of skill of those in the art.

The Examiner has asserted that undue experimentation would be required given the breadth of the claims, the lack of guidance and examples, the unpredictability in the art, the lack of guidance provided, the stare-of-the-art, and the quantity of experimentation required. However, upon review of each of the stated factors, Applicants respectfully disagree.

Breadth of claims

The first Wands factor discussed by the Examiner is the breadth of the claims. The Examiner contends that the claims, which are drawn to methods, plants, nucleic acids that hybridize to SEQ ID NO: 2 or encode a protein exhibiting less than 100% identity to SEQ ID NO: 3, and encoded proteins are not supported by an enabling disclosure.

As amended, all pending rejected claims relate to nucleic acid comprising a nucleotide sequence encoding SEQ ID NO: 3, nucleic acid comprising a nucleotide sequence that is at least 90% identical to SEQ ID NO: 2, nucleic acids that hybridize to SEQ ID NO: 2 under very high stringent wash conditions comprising at least one wash at 0.1x SSC, 0.1% SDS, at 60°C for 15 minutes, proteins encoded by the aforementioned nucleic acids, or proteins having least 45% sequence identity to SEQ ID NO: 3. Therefore, the breadth of the claims is not unduly broad.

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particularly given the recitation of specified sequences, specific percent identity limitations, and specific very high stringency hybridization conditions.

Unpredictability in the art

The second Wands factor addressed by the Examiner is the unpredictability in the art. Specifically, the Examiner asserts that "[w]ithout a recognized correlation between structure and function, those of ordinary skill in the art would not be able to identify without further testing which of those nucleic acids that hybridize to SEQ ID NO: 2 or encode a protein having at least 45% sequence identity to SEQ ID NO: 3 or encode conservative variants of SEQ ID NO: 3 would also have the same function as the protein of SEQ ID NO: 3" (Office Action, page 6, last paragraph).

As an initial matter, Applicants respectfully point out that the pending claims relating to a recombinant nucleic acid and an isolated protein do not include a functional limitation.

Regarding the claims which specify protein function, Applicant respectfully submit that while it cannot be predicted with one hundred percent accuracy which proteins encoded by nucleic acids that hybridize under high stringency conditions to SEQ ID NO: 2 or having amino acid sequences with at least 45% sequence identity to SEQ ID NO: 3 will exhibit the desired function, the disclosed sequences combined with the knowledge in the art of methods for analyzing sequence structure for conserved regions and domains provide a high degree of predictability that will provide one of skill in the art with a starting point. Therefore, despite the Office's allegations that proteins may be "sensitive to alterations in even a single amino acid in a sequence," one of skill in the art can use the disclosure of the specification to identify which altered proteins are likely to retain activity. By way of example, Figure 9 of the published application discloses amino acid sequences from other plant species that have less than 100% sequence identity to SEQ ID NO: 3, but that are still identifiable as PFT1 proteins. Using the ClustalW sequence alignment provided in Figure 9, one of skill in the art can easily determine which regions of the protein are more conserved than others.

One of skill in the art will understand that variance in amino acid residues between the sequences

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can give an indication of the nature of the changes that can be tolerated without disrupting the activity of the protein, as is discussed, for example at paragraph [0052] of the published application.

In making the enablement rejection, it appears that the Office is improperly relying on unpredictability as the primary basis for asserting lack of enablement. However, as discussed above, undue experimentation is evaluated based upon the multiple factors listed. It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above Wands factors while ignoring one or more of the others; instead, the Examiner's analysis must consider all the evidence related to each of these factors and any conclusion of nonenablement must be based on the evidence as a whole, § MPEP 21264.019(a).

Finally, even if one were to concede that there was a high level of unpredictability (which is denied), the facts of Wands make clear that an invention can be enabled even when there is a complete lack of predictability. In this case, the Federal Circuit held that claims to monoclonal antibodies directed to a particular protein are enabled even where the application only discloses the sequence of the protein. Clearly, with just the protein sequence, one of skill in the art could not predict the sequence of even a single monoclonal antibody, much less all monoclonal antibodies that could bind to the protein. Nevertheless, despite the complete lack of unpredictability of the sequence of the monoclonal antibodies encompassed by the claim, the Federal Circuit still found such claims to be enabled on the grounds that is was routine for one of skill to immunize an animal such as a rabbit with the protein, generate monoclonal hybridomas from the rabbit, and screen the hybridomas for monoclonal antibodies which are directed to the protein. Thus, Wands makes clear that other factors, such as the nature of the experimentation necessary, must be considered together with the degree of unpredictability when evaluating enablement, and are fully capable of compensating for even an extremely high degree of unpredictability.

Amount of guidance provided

The third Wands factor that the Examiner discusses is the level of guidance provided by the specification. The Examiner alleges that Applicants have not disclosed how one makes or Application No.: 10/560,652 15 Docket No.: 532792000800

isolates any of the sequences that are encompassed by Applicants' broad claims.

Applicants respectfully submit that the instant specification provides more than ample support for a recombinant nucleic acid comprising a nucleotide sequence that is at least 90% identical to SEQ ID NO: 2 and an isolated protein encoded by a nucleotide sequence hybridizing to SEQ ID NO: 2 under very high stringent wash conditions or having an amino acid sequence at least 45% identical to SEQ ID NO: 3. For example, paragraphs [0057], [0060], and [0067] of the published application describe using nucleic acid fragments derived from SEQ ID NO: 2 as probes for obtaining nucleic acids of interest by hybridizing said probes, under stringent wash conditions, to genomic or cDNA libraries to detect homologous nucleotide sequences. Further, paragraphs [0078] - [0083] describe methods for stable expression of proteins in host cells by using recombinant expression vectors, and isolation and purification of the recombinantly expressed proteins by immunological separation involving antibodies. Paragraph [0065] describes biochemical methods, such as proteolytic digestion, gel electrophoresis and/or microsequencing, for determining the sequence of polypeptides (i.e. proteins) of interest.

With regards to identifying proteins with the desired function and nucleic acids which encode these proteins, the Examiner alleges that the specification "fails to provide guidance for which amino acids of the protein encoded by SEQ ID NO: 2 can be altered, the type of alteration, and which amino acids must not be changed, to maintain activity of the encoded protein," (Office Action, page 7). Applicants respectfully submit that the specification also provides ample support for methods for designing or isolating and identifying nucleic acids that hybridize to SEQ ID NO: 2 under high stringency wash conditions that encode proteins retaining the function of the PFT1 protein encoded by SEQ ID NO: 3 and proteins having at least 45% sequence identity to SEQ ID NO: 3 that retain the function of the PFT1 protein encoded by SEQ ID NO: 3.

As discussed in the "Unpredictability" section, Applicants have provided in Figure 9 a ClustalW sequence alignment that one of skill in the art can use to determine which regions of the protein are more conserved than others and therefore less likely to tolerate significant variation. Application No.: 10/560,652 16 Docket No.: 532792000800

Applicants also provide ample description of methods for screening for desired nucleic acids/protein for function. For example, paragraph [0084] of the published application describes a method of generating a genetically modified plant having altered flowering time by contacting a plant cell with at least one expression vector containing the nucleic acid of interest to obtain a transformed plant cell, producing a plant from said transformed cell, and selecting a plant exhibiting altered flowering time. Plants that express any of the instantly claimed nucleic acids can be screened for altered flowering time, and can thus be identified by comparing the flowering time of the transformed plant to the flowering time of wild type plants by visual observation as described. for example, at paragraph [0116]. Regarding polypeptides, the specification discloses polypeptides that have been deliberately modified through site-directed mutagenesis, for example at paragraph [0049]; that may contain conservative variations such as substituting one hydrophobic residue for another, for example at paragraph [0051]; or that contain conserved regions, for example PFT1 amino acid sequences of other plant species as described, for example in figure 9. Furthermore, the specification discloses methods for identifying which of these described polypeptide have structural similarity to proteins encoded by SEQ ID NO: 3 through the use of Western blot analysis, for example at paragraph [0053], and which of these variants retain PFT1 activity by screening for polypeptides which, when expressed in plants modulate flowering time, as described above.

With regards to instantly pending claim 27, which is directed towards a recombinant nucleic acid that comprises a nucleotide sequence that is at least 90% identical to SEQ ID NO:2, and instantly pending but withdrawn claim 37, which is directed towards an isolated protein encoded by a nucleotide sequence hybridizing to SEQ ID NO: 2 under very high stringent wash conditions comprising at least one wash at 0.1 x SSC, 0.1% SDS, at 60°C for 15 minutes, the Office is reminded that all that is required for enablement is that the instant specification teach one of skill how to make and use the recombinant nucleic acid of claim 27 or the isolated protein of claim 37. As set forth above, the instant specification provides ample guidance for how to make the claimed recombinant nucleic acid and isolated protein. Furthermore, the instant specification provides guidance for the use of the claimed recombinant nucleic acid and isolated protein. For example, paragraph [0068] of the published application describes a method for using the recombinant nucleic

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acid as a probe in hybridization screens, and paragraph [0074] of the published application describes a method for using the isolated protein to screen for other proteins and compounds that bind to the isolated protein.

The Office's other specific assertions regarding Applicant's disclosure are discussed below.

The Office asserts that "Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe..." (Office Action, page 7, second full paragraph). The instant specification teaches how to determine which regions can be used for amplifications or for probes, for example, at paragraph [0068] of the published application.

The Office further asserts that with regard to claim 1, the instant specification does not provide guidance for the "multitude of methods" of altering the level of PFT1 in a plant. Applicants assert that methods for altering the level of proteins in an organism are well known in the art. Furthermore, the instant specification provides guidance for methods of altering the level of PFT1 in plants. For example, paragraph [0085] describes a method of reducing the expression of PFT1 in plants by transforming plants to express and produce an antisense polynucleotide specific for PFT1 or cosuppression by operatively linking a truncated form of a PFT1 gene to a promoter. Thus the instant specification provides ample guidance for multiple methods of altering the level of PFT1 in plants.

In view of the above, Applicants respectfully submit that the instant specification provides sufficient guidance to enable one of skill in the art to make and use the instantly claimed invention.

State of the art

The fourth Wands factor addressed by the Examiner is the state of the art. The Examiner asserts that "the state-of-the-art teaches that isolating DNA fragments using stringent hybridization

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wash conditions does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe," (Office Action, page 8, first full paragraph).

Applicants respectfully point out that none of the instantly pending claims require that the isolated DNA fragments have contiguous nucleotide sequences that are the same or nearly the same as the probe. At most, the claims only require that the fragment hybridize to SEQ ID NO: 2 under very high stringent wash conditions, for example instant claim 27. The Examiner also contends that Fourgoux-Nicol et al teach that the probe and isolated DNA fragment exhibited a number of sequence differences, but ignores the fact that in page 863, left column, 2nd full paragraph, Fourgoux-Nicol et al also teach that the isolated DNA fragment was "a longer but still partial clone [of the mRNA of interest], that had an "expression pattern [that]...appeared to be identical to the M3 [probe] pattern." Even though there were sequence differences between the probe and isolated DNA fragment, both retained the same expression pattern.

Furthermore, as discussed above, the state of the art is such that many routine methods are available to one of skill in the art to identify and screen which of the sequences that hybridize to SEQ ID NO: 2 under very high stringent wash conditions would retain PFT1 activity. Therefore the state of the art teaches how to identify and screen for nucleic acid sequences that hybridize to SEQ ID NO: 2 under very high stringent wash conditions comprising at least one wash at 0.1 x SSC, 0.1% SDS, at 60°C for 15 minutes or that encode a protein that is at least 45% identical to SEQ ID NO: 3, or conservative variants of SEQ ID NO: 3.

Ouantity of experimentation required

The fifth Wands factor discussed by the Examiner is the quantity of experimentation necessary to make and use the claimed invention based on the content of the disclosure. The Examiner alleges that "in the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences..." (Office Action, page 8, bottom).

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While one of skill in the art may have to conduct complex experimentation to obtain fragments of SEQ ID NO: 2 and regions of SEQ ID NO: 3, methods for conducting such experimentation are disclosed in the instant specification and are well established in the art. Applicants respectfully remind the Office that the fact that experimentation is complex does not necessarily make it undue if the art typically engages in such experimentation. All of the described experimentation is routine for those of skill in the art and therefore would not be considered undue regardless of the amount of experimentation that must be performed. Therefore the amount of experimentation required would not be undue.

Working examples

Another Wands factor is the existence of working examples. Example 2 of the instant specification is a working example showing how the gene that expresses PFT1 was identified, cloned, and expressed in plants. Furthermore, it is well established that working examples are not required to enable an invention. Thus this working example should be more that sufficient to enable the instantly claimed invention.

Nature of the invention

Yet another *Wands* factor is the nature of the invention. In this case, making and using the instantly claimed invention requires only routine molecular biology techniques and is a matter of routine screening of nucleic acid sequences that hybridize to SEQ ID NO: 2 under very high stringent wash conditions comprising at least one wash at 0.1 x SSC, 0.1% SDS, at 60°C for 15 minutes or that encode a protein that is at least 45% identical to SEQ ID NO: 3, or conservative variants of SEQ ID NO: 3.

Level of skill in the art

The final Wands factor is the level of skill in the art. The skill in the art is quite high.

The synthesis or isolation and identification of nucleic acid sequences that hybridize to SEQ ID NO:

2 under very high stringent wash conditions comprising at least one wash at 0.1 x SSC, 0.1% SDS.

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at 60°C for 15 minutes or that encode a protein that is at least 45% identical to SEQ ID NO: 3, or conservative variants of SEQ ID NO: 3, as well as plant transformation and screening for a plant phenotype (protein activity) are typically done by graduate level research scientists or higher. Such research scientists are well versed in the molecular biology and screening techniques required by the claimed invention.

Thus, given that most, if not all, of the enablement factors weigh in favor of Applicants, the instantly claimed invention would not require undue experimentation by one of skill in the art. Applicants thus respectfully assert that the presently pending claims 1-13, 23-24, and 27-36, as well as the currently withdrawn claims 14-22 and 37, are enabled under 35 U.S.C. § 112, first paragraph. Applicants therefore respectfully request that this basis for rejection be withdrawn.

VIII. Claim Rejections - 35 USC § 102(b)

Claims 25-28 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Lin et al (2001, NCBI Accession Number AC079281). The Examiner alleges that Lin et al disclose a sequence that exhibits 67% sequence similarity to the instantly claimed SEQ ID NO: 2, and that the sequence encodes an amino acid sequence that exhibits 83% identity to the instantly claimed SEQ ID NO: 3.

To the extent the rejections are applicable to the amended claims, Applicants respectfully traverse the rejection and its supporting remarks. Anticipation requires that a single reference disclose each and every limitation of the claims.

Claim 25 is directed to a recombinant nucleic acid comprising SEQ ID NO: 2. As acknowledged by the Examiner, Lin at all do not disclose a recombinant nucleic acid with a nucleic acid sequence that is 100% identical to SEQ ID NO: 2. Thus Lin et al. does not anticipate claim 25.

Claim 26 is directed to a recombinant nucleic acid comprising a nucleotide sequence encoding SEQ ID NO:3. As acknowledged by the Examiner, the amino acid sequence encoded by Lin et al. is not identical to SEQ ID NO: 3. Thus Lin et al. also fails to anticipate claim 26.

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Claim 27 is directed to a recombinant nucleic acid comprising a nucleotide sequence that is at least 90% identical to SEQ ID NO: 2. As determined using the ClustalW 2.0 program (available online at http://www.ebi.ac.uk/Tools/clustalw2/index.html) using DNA identity matrix (alignment algorithm), GAPOPEN: 15 (penalty for opening gaps), GAPEXT: 6.66 (penalty for extending gaps), and GAPDIST: 4 (penalty for gap distance) as parameters, the alignment score (% identity) between Lin et al. and SEQ ID NO: 2 is only 87%. Thus, Lin et al. also fails to anticipate claim 27.

Claim 28 has been canceled

Applicant therefore respectfully request that this basis for rejection be withdrawn,

IX. Claim Rejections - 35 USC § 101

Claim 34 is rejected under 35 U.S.C. 101 because the claimed invention is allegedly directed to non-statutory subject matter. The Examiner contends that due to the Mendelian model of gene inheritance, "it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature."

Applicants respectfully assert that the rejection is moot in view of the instantly pending claim 34, which is drawn to a "seed comprising a recombinant expression vector" Applicants therefore respectfully request that this basis for rejection be withdrawn.

X. Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 53279200800. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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